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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,511	07/29/2003	John C. Jeppesen	6553-0501	6911

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EXAMINER	
BUNIN, ANDREW M	
ART UNIT	**PAPER NUMBER**
3743	

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/629,511	JEPPESEN, JOHN C.	
	Examiner	Art Unit	
	Andrew M. Bunin	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,6,8-11,13,15-23,25,28,29 and 31-39* is/are pending in the application.

4a) Of the above claim(s) *1-3,5,6,8-11,13,15-17,22,37 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-21,23,25,28,29,31-36 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 1-3, 5, 6, 8-11, 13, 15-17, 22, 37, and 38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/25/05.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein (US 6012455). Goldstein discloses a dual arch 24 oral appliance for obturating the oral cavity of the patient thereby preventing mouth venting of PAP. Goldstein disclose the oral appliance further having an anterior, extraoral slide 122 or 202/204 affixed thereto positioning the oral appliance within a patient's upper and lower dental arches capable of maintaining the patient's mandible in a substantially neutral centric position without protrusion of the mandible. Goldstein has also disclosed a pair of PAP tubing 118/120 and connecting one distal end of each tube to an external source of positive airway pressure (Figure 15). In addition, Goldstein discloses a PAP tubing retention platform 112/200 mounted to the slide 122 or 202/204. The PAP tubing

118/120 is also operatively connected to the PAP tubing retention platform 112. Goldstein has taught inserting the other end of each tubing 118/120 into a respective nasal cavity for delivery of air from an external source as shown in Figure 15. The patients nares are sealed with the nasal pillows 124/126. Although Goldstein doesn't teach the method of forming these features, Goldstein has anticipated the structure implied by the steps. Therefore, a 35 USC 103 rejection may be made and the burden is shifted to the applicant to show an unobvious difference.

As for claim 19, Goldstein doesn't explicitly state the positioning of the PAP tubing retention platform 112 and the PAP tubing 118 anterioposteriorly to a position within a range of 5 mm to 30 mm from the labial surface of the maxillary anterior teeth. However, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Goldstein for positioning of the PAP tubing retention platform 112 and the PAP tubing 118 anterioposteriorly to a position within a range of 5 mm to 30 mm from the labial surface of the maxillary anterior teeth for a variety of users with different measurements based on age and facial structures. It is noted that applicant's specification does not set forth this range as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art. Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Claims 20, 21, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein in view of Landis et al. (US 5477852). Goldstein discloses everything except the PAP tubing retention platform as being composed of an acrylic material that is at least 3 mm thick. However, Landis et al. disclose a similar Nasal PAP apparatus that is composed of an acrylic material (column 13, lines 61-66) that is at least 3 mm thick (column 12, line 39). Landis et al. has taught that it is well known in the art at the time of the invention to build PAP apparatus from acrylic and teaches the thickness used to be between 2 and 6 mm which anticipates a 3 mm thickness. In addition, it is noted that applicant's specification does not set forth acrylic as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art. Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish this claim over the prior art, barring a convincing showing of evidence to the contrary.

As for claims 21 and 23, Landis et al. disclose the acrylic material as being adjusted to optimize a desired angulation via application of heat (column 12, lines 41-47) (column 4, lines 40-42). Landis et al. also disclose the PAP device as being created via injection molding (column 13, line 66). Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Goldstein with the 3 mm thick acrylic taught by Landis et al. PAP device for the PAP tubing retention platform in order for the device to maintain flexibility without breaking.

Claims 25 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein in view of Singer et al. (US 5823193). Goldstein has taught everything except an obturator comprising an exterior surface made from acrylic material lined with an elastomeric material. However, Singer et al. disclose a similar obturator for alleviating snoring. Singer et al. disclose the obturator 10 comprising an exterior surface 32/34 made from an acrylic material lined with an elastomeric material 28/30 (column 4, lines 20-29) (abstract). Singer et al. continue to disclose a hard exterior acrylic 32/34 and deposited with an elastomeric material 28/30. Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Goldstein with exterior acrylic material for protecting the teeth against grinding and an inner elastomeric material for conforming to the teeth and cushioning the jaw against impact forces.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein in view of Landis et al. Goldstein discloses the anterior extraoral slide 142 is bonded to the anterior surface of the oral appliance 130 without the use of metal parts as shown in Figure 18. However, Goldstein doesn't teach the slide acrylically bonded to the oral appliance. It is noted that applicant's specification does not set forth acrylic bond as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art. Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish this claim over the prior art, barring a convincing showing of evidence to the

contrary. Landis et al. disclose a similar Nasal PAP apparatus that is composed of an acrylic material (column 13, lines 61-66). Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Goldstein with the acrylic bond for maintaining a strong connection between the slide and an oral appliance.

Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein in view of Katz et al. (US 2004/0115139). Goldstein discloses everything except the oral appliance as being fabricated from a three-dimensional bite registration for orienting the position of the upper and lower dental arches. However, Katz et al. has taught the aspect of fabricating an oral appliance such as a denture from a three-dimensional bite registration for orienting the position of the upper and lower dental arches (paragraphs 142-146). In addition, Katz et al. has also taught the bite registration as being produced utilizing Transcutaneous Electrical Nerve Stimulation (TENS) (paragraph 146, lines 6). Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Goldstein so its made from a three-dimensional bite registration via TENS as taught by Katz et al. in order to achieve optimal dental function, stability, and harmony of the stomatognathic system.

Claims 33-35 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein. Goldstein discloses a dual arch oral appliance 92 for placement

substantially within the oral cavity of a patient (Figure 15). Goldstein continues to disclose a retention platform 94 operably connected to the oral appliance 92 for positioning aneriorially of the patient's mouth (Figure 15). Goldstein also discloses a pair of air supply tubes 100/102 retained by the retention platform 94. Through the drawings, Goldstein teaches the dual arch oral appliance 92 within a patient's oral cavity and engagement of one arch of the oral appliance to the patient's mandibular arch and the other arch of the oral appliance to the patient's maxillary arch by the patient closing the oral cavity (see Figures 1,4,9, 11, 14, 19, and 20). Goldstein's device is capable of engagement without protrusion of the mandible and locating a neutral centric position with respect to the maxillary arch. Goldstein has continued to disclose positioning the end of each tube 100/102 within a respective nostril, connecting the distal ends of each tube to an air supply source, and delivering an air flow to the patient from the air supply source through the pair of tubes as shown in Figure 14. The device of Goldstein is capable meeting the steps of supporting and stabilizing tubes connected to the dual arch (Figure 15). Although Goldstein doesn't teach the method of forming these features, Goldstein has anticipated the structure implied by the steps. Therefore, a 35 USC 103 rejection may be made and the burden is shifted to the applicant to show an unobvious difference.

As for claims 35 and 39, Goldstein discloses connecting the tubes 100/102to the PAP tubing retention platform 94 and sealing both patient's nares with each nare being sealed using the nasal pillow 106/108 operably connected to a portion of the respective tubing positioned within a nostril (Figure 15). However, Goldstein doesn't teach the

steps of selecting a PAP tubing retention platform 94 appropriately sized for the patient's nasal features and/or width. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to select a PAP tubing retention platform sized for a patient's nasal features or width since it was known in the art that such apparatus are manufactured to fit a variety of users with different measurements based on age and facial structures.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein in view of Katz et al. Goldstein discloses everything except the step of obtaining a three-dimensional bite registration in a neutral centric position via Transcutaneous Electrical Nerve Stimulation (TENS). However, Katz et al. has taught obtaining a three-dimensional bite registration in a neutral centric position via Transcutaneous Electrical Nerve Stimulation (TENS) (paragraphs 142-146) (especially paragraph 146, lines 6). Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Goldstein so its made from a three-dimensional bite registration via TENS as taught by Katz et al. in order to achieve optimal dental function, stability, and harmony of the stomatognathic system.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: US 4472140, US 4782837, US 4676257, US 5752510, US 6209542, US 5365945, US 5117816, and US 6571798

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Bunin whose telephone number is (571)272-4801. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571)272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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